

VISIT...

LANZAROTE
Caliente.COM

National Medical Policy

Subject: Artificial Retina

Policy Number: NMP349

Effective Date*: June 2007

Updated: June 2016

**This National Medical Policy is subject to the terms in the
IMPORTANT NOTICE
at the end of this document**

For Medicaid Plans: Please refer to the appropriate State's Medicaid manual(s), publication(s), citation(s), and documented guidance for coverage criteria and benefit guidelines prior to applying Health Net Medical Policies

The Centers for Medicare & Medicaid Services (CMS)

For Medicare Advantage members please refer to the following for coverage guidelines first:

Use	Source	Reference/Website Link
	National Coverage Determination (NCD)	
	National Coverage Manual Citation	
	Local Coverage Determination (LCD)*	
	Article (Local)*	
	Other	
X	None	Use Health Net Policy

Instructions

- Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.
- Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under "Reference/Website" and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region. ***Note: Health Net must follow local coverage determinations (LCDs) of Medicare Administration Contractors (MACs) located outside their service area when those MACs have exclusive coverage of an item or service. (CMS Manual Chapter 4 Section 90.2)**
- If more than one source is checked, you need to access all sources as, on occasion, an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.
- If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

Current Policy Statement

Health Net, Inc. considers the Argus II Retinal Prosthesis System medically necessary, when provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA). Per the HDE, the device is intended for individuals with severe to profound retinitis pigmentosa who meet the following criteria:

- Adults, age 25 years or older.
- Bare light or no light perception in both eyes. (If the patient has no residual light perception, then evidence of intact inner layer retina function must be confirmed.)
- Previous history of useful form vision.
- Aphakic or pseudophakic. (If the patient is phakic prior to implant, the natural lens will be removed during the implant procedure.)
- Patients who are willing and able to receive the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation.

Codes Related To This Policy

NOTE:

The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all inclusive.

On October 1, 2015, the ICD-9 code sets used to report medical diagnoses and inpatient procedures have been replaced by ICD-10 code sets.

ICD-9 Codes

362.50 Macular degeneration (senile), unspecified
362.74 Pigmentary retinal dystrophy

ICD-10 Codes

H35.30 Unspecified macular degeneration
H35.52 Pigmentary retinal dystrophy

CPT Codes

0100T Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy

HPCS Codes

N/A

Scientific Rationale – Update June 2015

Chuang et al. (2014) completed a systematic review and compared selected retinal implant models by examining publications describing five representative retinal prostheses: Argus II, Boston Retinal Implant Project, Epi-Ret 3, Intelligent Medical Implants (IMI) and Alpha-IMS (Retina Implant AG). Publications were analyzed using three criteria for interim success: clinical availability, vision restoration potential and long-term biocompatibility. Clinical availability: Argus II is the only device with FDA approval. Argus II and Alpha-IMS have both received the European CE Marking. All

others are in clinical trials, except the Boston Retinal Implant, which is in animal studies. Vision restoration: resolution theoretically correlates with electrode number. Among devices with external cameras, the Boston Retinal Implant leads with 100 electrodes, followed by Argus II with 60 electrodes and visual acuity of 20/1262. Instead of an external camera, Alpha-IMS uses a photodiode system dependent on natural eye movements and can deliver visual acuity up to 20/546. Long-term compatibility: IMI offers iterative learning; Epi-Ret 3 is a fully intraocular device; Alpha-IMS uses intraocular photosensitive elements. The authors concluded that based on the review of these three criteria, Alpha-IMS is the most likely to achieve long-term success decades later, beyond current clinical availability.

Rizzo et al. (2014) studied the anatomical and functional outcomes of Argus II Retinal Prosthesis System implantation in retinitis pigmentosa patients in 6 patients with a visual acuity no better than light perception. Implantation of the Argus II Retinal Prosthesis System was safely performed in all patients. One patient experienced postoperative elevation in intraocular pressure, which was controlled medically. In one patient, moderate detachment of the choroid occurred postoperatively, which resolved spontaneously. One patient withdrew from the study. Wound dehiscence, endophthalmitis, or retinal detachment was not observed. All patients were able to locate a bright light on the ceiling and a dark line on the floor after the surgery. Performance in square localization tests improved in 4 patients, and direction of motion improved in 3 patients. One patient achieved grating visual acuity. Goldmann visual field test results improved in all patients. The authors concluded that the patients showed an improvement in visual tasks after the surgery, and the device was well tolerated and functional over a 1-year follow-up period. According to the authors, a rigorous patient selection process is necessary to maximize patient compliance with the rigorous follow-up testing schedule and lengthy, difficult rehabilitation process. While the results of this study are promising, prospective randomized studies with long-term follow-up are needed to evaluate the safety and efficacy of retinal prosthetic devices.

Scientific Rationale – Update June 2013

Retinitis pigmentosa (RP) comprises a group of inherited conditions that cause progressive retinal degeneration and affect the photoreceptors and retinal pigment epithelium. A family history is identified in about 70 percent of patients. Night blindness is one of the earliest symptoms, but can be so gradual that it may go unnoticed by patients. Loss of visual field is progressive, starting in the midperiphery and progressing more peripherally, resulting in a constricted visual field.

In February 2013, the United States Food and Drug Administration (FDA) approved the Argus II Retinal Prosthesis System under the humanitarian device exemption (HDE) application (i.e., The device is exempt from demonstrating effectiveness but there must be sufficient information to show a probable benefit for its intended use and indication for use). The approval was based in part on a clinical study of 30 participants with RP who received the Argus II Retinal Prosthesis System. Investigators monitored the participants for adverse events related to the device or to the implant surgery and regularly assessed their vision for at least 2 years after receiving the implant. Following the implant surgery, 19 of 30 study patients experienced no adverse events related to the device or the surgery. Eleven study patients experienced a total of 23 serious adverse events, which included erosion of the conjunctiva, dehiscence (splitting open of a wound along the surgical suture), retinal detachment, inflammation, and hypotony (low intraocular pressure).

Per the FDA, "Pre-clinical in vitro and in vivo testing demonstrated the Argus II Retinal Prosthesis System meets applicable international standards and Second Sight-defined design requirements. A 6 patient feasibility study with a first generation device (Argus 16) demonstrated that a retinal prosthesis could be implanted chronically in human subjects. Long-term data collected from this study demonstrated the safety and proof of concept that an electrode array could be used to stimulate the retina to elicit visual percepts in blind subjects. Data from the Argus 16 study provided important design input for the next generation implant (Argus II), external equipment, and stimulation fitting strategies.

A 30 subject prospective clinical trial was conducted which demonstrated that the Argus II System is safe and will provide a probable benefit to the indicated patient population. All subjects in the clinical trial had been implanted a minimum of 2.5 years follow-up data, with several subjects having over 4 years of follow-up data. The long-term safety results are acceptable, with the majority of events resolving with no or minimal intervention. Serious adverse events were clustered in a few subjects and most occurred within the first 6 months post-implant. Furthermore, based on a trend toward reduced adverse events as the trial progressed and more experience was gained with the device, it is likely that the safety profile of the Argus II System will continue to improve with increasing surgical experience with these devices. The risk, therefore, is acceptable, especially when considering that the adverse events are occurring in blind eyes, for which decreased vision is not a significant risk. The performance analysis showed that a majority of subjects using the Argus II System have improved visual function that ranged between subjects from light perception to at least hand motion, or counting fingers vision. Assessments of subjects in their normal environments by low vision therapists also demonstrated that the majority of subjects received positive effects from the Argus II System in terms of well being and/or functional vision. These results represent a significant improvement and benefit for these subjects, especially when considering that they have no other approved treatment options for their irreversible degenerative disease. When considering all the data, it has been demonstrated that the Argus II System poses an acceptable risk to people with severe to profound retinitis pigmentosa in exchange for a probable benefit - that of improvements in visual function, functional vision, and/or well-being."

Per the approval, the device is indicated for use in patients with severe to profound retinitis pigmentosa who meet the following criteria:

- Adults, age 25 years or older.
- Bare light or no light perception in both eyes. (If the patient has no residual light perception, then evidence of intact inner layer retina function must be confirmed.)
- Previous history of useful form vision.
- Aphakic or pseudophakic. (If the patient is phakic prior to implant, the natural lens will be removed during the implant procedure.)
- Patients who are willing and able to receive the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation.

The Argus II implant is intended to be implanted in a single eye, typically the worse-seeing eye.

The HDE was approved subject to the post-approval requirements that include two post-approval studies, (.ie., Extended Follow-up of the Argus II Retinal Stimulation

System Feasibility Study and New Enrollment Argus II Retinal Prosthesis System Post Approval Study)

Contraindications:

- Ocular diseases or conditions that could prevent the Argus II System from working (e.g. optic nerve disease, central retinal artery or vein occlusion, history of retinal detachment, trauma, severe strabismus, etc.).
- Ocular structures or conditions that could prevent the successful implantation of the Argus II Implant or adequate healing from surgery (e.g. extremely thin conjunctiva, axial length <20.5 mm or >26 mm; corneal ulcers, etc.).
- Ocular diseases or conditions (other than cataracts) that prevent adequate visualization of the inner structures of the eye (e.g. corneal opacity, etc.).
- Inability to tolerate general anesthesia or the recommended antibiotic and steroid regimen associated with the implantation surgery.
- Metallic or active implantable device(s) (e.g. cochlear implant) in the head.
- Any disease or condition (e.g. significant cognitive decline, etc.) that prevents understanding or communication of informed consent, fitting of the Argus II System, or post-operative follow-up. A pre-operative psychological evaluation may be recommended to confirm the patient is not contraindicated based on this criterion.
- Predisposition to eye rubbing.

Individuals implanted with an Argus II Implant should not undergo short wave or microwave diathermy; electroconvulsive therapy (ECT) or monopolar electrosurgical equipment. If lithotripsy or high output ultrasound must be used, the treatment beam should not focus near the Argus II Implant. The Argus II Implant has been classified as an MR Conditional device thus individuals with an Argus II Implant may undergo a magnetic resonance imaging (MRI) procedure ONLY if it is performed using a 1.5 or 3.0 Tesla MRI System according to instructions per device package insert. In addition, the Argus II System may interfere with the operation or accuracy of medical monitoring, diagnostic or life support equipment.

The FDA approval notes that at any time after implantation, Argus II patients have a risk of conjunctival complications which, if left untreated, may result in conjunctival erosion which could lead to endophthalmitis. The FDA also notes that the long-term effects of chronic electrical stimulation are unknown. Such effects may include deterioration of the retina or optic nerve. These effects may lead to deterioration of residual native vision and/or visual response to the Argus II System and could preclude subsequent replacement of the Argus II Implant with another retinal implant.

Dorn et al (2013) investigated the ability of 28 blind subjects implanted with a 60-electrode Argus II retinal prosthesis system to detect the direction of a moving object. Blind subjects (bare light perception or worse in both eyes) with retinitis pigmentosa were implanted with the Argus II prosthesis as part of a phase 1/2 feasibility study at multiple clinical sites worldwide. The experiment measured their ability to detect the direction of motion of a high-contrast moving bar on a flatscreen monitor in 3 conditions: with the prosthesis system on and a 1-to-1 mapping of spatial information, with the system off, and with the system on but with randomly scrambled spatial information. Fifteen subjects (54%) were able to perform the task significantly better with their prosthesis system than they were with their residual vision, 2 subjects had significantly better performance with their residual vision, and no difference was found for 11 subjects. Of the 15 better-performing subjects, 11

were available for follow-up testing, and 10 of them had significantly better performance with normal rather than with scrambled spatial information. Investigators concluded this work demonstrates that blind subjects implanted with the Argus II retinal prosthesis were able to perform a motion detection task they could not do with their native vision, confirming that electrical stimulation of the retina provides spatial information from synchronized activation of multiple electrodes. (clinicaltrials.gov Identifier:NCT00407602)

da Cruz et al (2013) reported on a prospective, internally controlled, multicentre trial of the Argus II system. Twenty-eight subjects with light perception vision received a retinal implant. Controlled, closed-group, forced-choice letter identification, and, open-choice two-, three- and four-letter word identification tests were carried out. The mean±SD percentage correct letter identification for 21 subjects tested were: letters L, T, E, J, F, H, I, U, 72.3±24.6% system on and 17.7±12.9% system off; letters A, Z, Q, V, N, W, O, C, D, M, 55.0±27.4% system on and 11.8%±10.7% system off, and letters K, R, G, X, B, Y, S, P, 51.7±28.9% system on and 15.3±7.4% system off. ($p < 0.001$ for all groups). A subgroup of six subjects was able to consistently read letters of reduced size, the smallest measuring 0.9 cm (1.7°) at 30 cm, and four subjects correctly identify unrehearsed two-, three- and four-letter words. Average implant duration was 19.9 months. Investigators concluded multiple blind subjects fitted with the Argus II system consistently identified letters and words using the device, indicating reproducible spatial resolution. This, in combination with stable, long-term function, represents significant progress in the evolution of artificial sight.

Scientific Rationale – Update June 2012

There are currently a large number of ongoing Clinical Trials on a variety of different retinal prostheses. None of the trials have study results posted at this time.

The U.S. Food and Drug Administration (FDA), has a research project on safety of electrical stimulation in the retina (4/23/2012). It notes the following:

“Retinal prostheses seek to stimulate the degenerated retinal network in visually impaired patients to elicit a sensation of light termed a ‘phosphene’. Little is known about what levels of electrical stimulation are safe for the retina. The objective of this project is to determine safer and more effective methods of nerve cell stimulation. We use the retina, a CNS-derived piece of neural tissue as a model system. Using optical, physiological, bioimpedance, and computational methods, we are determining the safety of electrical stimulation for activating the neurons in the retinal network. We are currently measuring the resistivity and permittivity of the tissue layers forming the rabbit eye wall. In a collaboration with the Peixoto lab (George Mason Univ), this has allowed us to predict the propagation of the electric field by stimulus electrodes. We have also developed a novel optical coherence tomography method to observe neurons directly under a transparent stimulation electrode during pulse train stimulation. Retinal tissue swelling and layer deformation can now be observed during stimulation in real time. The results of this project will provide FDA with a better understanding of how the retinal layers are activated by electrical stimulation pulses and help determine what levels of electrical stimulation are safe for retinal tissue”.

On April 17, 2009, the U.S. FDA developed a 'Draft Guidance for Industry and FDA Staff: Investigational Device Exemption (IDE) Guidance for Retinal Prostheses'. It states the following:

"This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance".

At this time, there is no indication on the U.S. FDA site that this 'Draft Guidance' has been finalized.

Scientific Rationale – Update June 2010

According to website of the U.S. Department of Energy's (DOE's) Artificial Retina Project, as of mid-July 2009, a second model integrating a 60-electrode array has been implanted in 30 human subjects domestically and internationally. A third model, an array with a higher electrode count, is under development.

Scientific Rationale – Update June 2009

According to website of the U.S. Department of Energy's (DOE's) Artificial Retina Project, three models are now in development or testing. Model 1, with 16 electrodes, has been implanted in six patients. As of March 2009, a second model integrating a 60-electrode array has been implanted in 21 human subjects domestically and internationally. A third model, an array with a higher electrode count, is under development.

Scientific Rationale

The retina is a multi-layered light-sensitive tissue that lines the back of the eye. It is designed to convert photons into neural impulses that travel along the visual pathways to the visual cortex. The retina contains millions of photoreceptors (rods and cones) that capture light rays and convert them into electrical impulses. These impulses travel along the optic nerve to the brain where they are turned into images. There are many inherited and acquired diseases or disorders that may affect the retina leading to visual loss or complete blindness. Profound vision loss due to pathology in the retina or the retinal pigment epithelium (RPE) currently has no practical treatment options or effective means of restoring vision.

Retinal prosthetic devices are currently being investigated in an effort to partially restore functional vision in patients with moderate to severe vision impairment caused by retinal degeneration by electrically stimulating functional neurons in the retina. The implants are being developed to help people with degenerative diseases of the retina such as retinitis pigmentosa (RP) and age-related macular degeneration (AMD). All retinal implants require an intact optic nerve pathway to allow them to function. Currently, two approaches are being investigated for retinal prosthesis, subretinal and epiretinal. With the subretinal implants, the device is placed between the retinal pigment epithelium (RPE) cells and the remaining retinal layers and is designed to replace photoreceptors in the retina. The epiretinal approach is designed to communicate directly with the ganglion and bipolar cells. This device is placed on the vitreal surface of the retina.

Drs. Alan and Vincent Chow, co-founders of the Optobionics Corporation developed the Artificial Silicone Retina (ASR), a subretinal implant. The implant, which is 2 mm in diameter and 0.001 inch in thickness, is a microelectrode array powered by approximately 3,500 microscopic solar cells. These solar cells are intended to replace the function of the retina's distance-damaged light-sensing cells. Light that strikes the chip is converted to electric currents that stimulate visual signals in remaining functional retinal cells. These signals are sent via the optic nerve to the brain. The ASR implant has been in clinical trials since June 2000 and was implanted in 6 patients with RP in a two-year safety and feasibility study.

Another device currently under investigation is the Argus 16 (Second Sight), an epiretinal chip that consists of a tiny camera and transmitter mounted in eyeglasses, an implanted receiver, and an electrode-studded array that is secured to the retina with a microtack. A wireless microprocessor and battery pack worn on the belt powers the entire device. The camera on the glasses captures an image and sends the information to the video processor, which converts the image to an electronic signal and sends it to the transmitter on the sunglasses. The implanted receiver wirelessly receives this data and sends the signals through a tiny cable to the electrode array, stimulating it to emit electrical pulses. The pulses induce responses in the retina that travel through the optic nerve to the brain, which perceives patterns of light and dark spots corresponding to the electrodes stimulated. Patients learn to interpret the visual patterns produced into meaningful images. The first generation Argus 16 implant consists of a 16 electrode array and a relatively large implanted receiver implanted behind the ear. According to the manufacturer, this device will be studied in a multicenter worldwide trial with five sites in North and South America and five sites in Europe. The follow-up will be roughly 3 years. Recently, the US FDA investigational device exemption (IDE) has been granted to begin clinical trials for the Argus II, designed with 60 electrode array and a much smaller receiver that is implanted around the eye. The Array II may provide implanted subjects with higher resolution images.

Another device, still in the early stages of experimentation, by the Retinal Implant Project, includes two silicon computer chips, both measuring 2 mm by 2 mm. One chip receives light and converts it to electricity for use by the other. The first chip is a signal processor, mounted on a pair of glasses along with a camera. It captures an image and transmits it wirelessly to a second chip embedded in the eye. The embedded chip is implanted onto the innermost layer of the retina that contains ganglion cells, and stimulates those cells with electricity. Several other retinal implant devices are also in the early stages of development or in clinical trials in Europe.

Chow et al. (2004) investigated the safety and efficacy of the artificial silicon retina (ASR) microchip in six patients with retinitis pigmentosa (RP). The device was implanted in the right eyes of six patients, the left eyes served as controls. During follow-up that ranged from 6 to 18 months, all ASRs functioned electrically. No patient showed signs of implant rejection, infection, inflammation, erosion, neovascularization, retinal detachment, or migration. Visual function improvements occurred in all patients and included unexpected improvements in retinal areas distant from the implant. Subjective improvements included improved perception of brightness, contrast, color, movement, shape, resolution, and visual field size. The author concluded that the observation of retinal visual improvement in areas far from the implant site suggests a possible generalized neurotrophic-type rescue effect on

the damaged retina caused by the presence of the ASR. A larger clinical trial is indicated to further evaluate the safety and efficacy of a subretinally implanted ASR.

In a prospective, investigational device exemption trial, Yanai et al. (2007) assessed visual task performance in three blind patients with retinitis pigmentosa (RP) who were implanted with epiretinal prostheses. A prototype retinal prosthesis was implanted in the eye with worse light sensitivity. The prosthesis had 4 x 4 array of platinum electrodes tacked to the epiretinal surface. The prosthesis was wirelessly controlled by a computer or by a head-worn video camera. Visual function testing was performed in single masked or double masked fashion. Scores from the visual task were compared to chance to determine statistical significance. The investigator found that the patients performed significantly better than chance in 83% of the tests. Using the video camera, subjects scored as follows on simple visual tasks: locate and count objects (77% to 100%), differentiate three objects (63% to 73%), determine the orientation of a capital L (50% to 77%), and differentiate four directions of a moving object (40% to 90%). A subset of tests compared camera settings using multipixels vs single pixels. Using multipixel settings, subjects performed better (17%) or equivalent (83%) in accuracy and better (25%) or equivalent (75%) in reaction time.

According to the developer of the epiretinal implant, an IDE trial of the first generation implant (Argus 16), which has 16 electrodes, is ongoing. According to the manufacturer, the Argus 16 was implanted in six RP patients between 2002 and 2004 and has enabled them to detect when lights are on or off, describe an object's motion, count discrete items, as well as locate and differentiate basic objects in an environment.

In summary, retinal implants are at a very early stage of development. Data in the published peer-review literature is limited. At the present time, no device has received final approval for marketing by the U.S. Food and Drug Administration (FDA). The long term safety and effectiveness of these devices needs to be validated in large clinical trials.

Review History

June 2007	Medical Advisory Council
June 2008	Update – no revisions
June 2009	Update – no revisions
June 2010	Update – no revisions
June 2011	Update. Added Medicare Table. No revisions.
June 2012	Update. No Revisions
June 2013	Update – Added Argus II Retinal Prosthesis System as medically necessary, when provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA). Code Updates.
June 2014	Update - no revisions. Code Updates.
June 2015	Update – no revisions. Code Updates.
June 2016	Update – no revisions. Code updates.

This policy is based on the following evidence-based guideline:

1. American Academy of Ophthalmology (AAO). Microelectronic retinal implants. AAO Rapid Clinical Report. San Francisco, CA: AAO; August 2000.

References – Update June 2016

1. Ghezzi D. Retinal prostheses: progress toward the next generation implants. *Front Neurosci.* 2015; 9: 290. doi: 10.3389/fnins.2015.00290
2. Lin TC, Chang HM, Hsu CC, et al. Retinal prostheses in degenerative retinal diseases. *J Chin Med Assoc.* 2015 Sep;78(9):501-5. doi: 10.1016/j.jcma.2015.05.010. Epub 2015 Jun 30.
3. Nayagam DA, Durmo I, McGowan C, et al. Techniques for Processing Eyes Implanted with a Retinal Prosthesis for Localized Histopathological Analysis: Part 2 Epiretinal Implants with Retinal Tacks. *Vis Exp.* 2015; (96): 52348. doi: 10.3791/52348

References – Update June 2015

1. Chuang AT, Margo CE, Greenberg PB. Retinal implants: A systematic review. *Br J Ophthalmol.* 2014;98(7):852-856.
2. Kotecha A, Zhong J, Stewart D, et al. The Argus II prosthesis facilitates reaching and grasping tasks: A case series. *BMC Ophthalmol.* 2014;14:71.
3. Luo YH, da Cruz L. A review and update on the current status of retinal prostheses (bionic eye). *Br Med Bull.* 2014;109:31-44.
4. Rizzo S, Belting C, Cinelli L, et al. The Argus II Retinal Prosthesis: Twelve-Month Outcomes from a Single-Study Center. *Am J Ophthalmol.* 2014 Feb 19. pii: S0002-9394(14)00103-2.
5. Stronks HC, Dagnelie G. The functional performance of the Argus II retinal prosthesis. *Expert Rev Med Devices.* 2014;11(1):23-30.

References – Update June 2014

1. Garg S. Retinitis pigmentosa: Treatment. UpToDate. July 2013.
2. U.S. Food & Drug Administration. (FDA). FDA approves first retinal implant for adults with rare genetic eye disease. February 14, 2013.

References – Update June 2013

1. Ahuja AK, Dorn JD, Caspi A, et al. Blind subjects implanted with the Argus II retinal prosthesis are able to improve performance in a spatial-motor task. *Br J Ophthalmol.* 2011 Apr;95(4):539-43.
2. ClinicalTrials.gov. Retinal prosthesis.
3. da Cruz L, Coley BF, Dorn J, et al. The Argus II epiretinal prosthesis system allows letter and word reading and long-term function in patients with profound vision loss. *Br J Ophthalmol.* 2013 May;97(5):632-6.
4. Dorn JD, Ahuja AK, Caspi A, et al. The Detection of Motion by Blind Subjects With the Epiretinal 60-Electrode (Argus II) Retinal Prosthesis. *JAMA Ophthalmol.* 2013 Feb;131(2):183-9.
5. Dorn JD, Ahuja AK, Caspi A, et al. The Detection of Motion by Blind Subjects With the Epiretinal 60-Electrode (Argus II) Retinal Prosthesis. *Arch Ophthalmol.* 2012 Oct 8;1-7.
6. Hayes News. FDA Approves First Retinal Implant for Adults with Rare Genetic Eye Disease. Feb 2013.
7. Humayun MS, Dorn JD, da Cruz L, et al. Interim results from the international trial of Second Sight's visual prosthesis. *Ophthalmology.* 2012 Apr;119(4):779-88.

8. U.S. Food and Drug Administration. Argus II Retinal Prosthesis System. Feb 2013.

R

References – Update June 2012

1. ClinicalTrials.gov. Retinal prosthesis. Bethesda, MD: National Institutes of Health. 2011.
2. U.S. Food and Drug Administration (FDA). Research Project: Safety of Electrical Stimulation in the Retina. 4/23/2012.
3. U.S. Food and Drug Administration (FDA). Draft Guidance for Industry and FDA Staff: Investigational Device Exemption (IDE) Guidance for Retinal Prostheses. April 17, 2009.

References – Update June 2011

1. Chiang A, Haller JA. Vitreoretinal disease in the coming decade. Curr Opin Ophthalmol. 2010;21(3):197-202.
2. Ahuja, AK, Dorn, JD, Caspi, A, et al. Blind subjects implanted with the Argus II retinal prosthesis are able to improve performance in a spatial-motor task. Br J Ophthalmol. 2010 Sep 29.

References – Update June 2010

1. Artificial Retina Project. Last updated Dec 2009.
2. Chader GJ, Weiland J, Humayun MS. Artificial vision: needs, functioning, and testing of a retinal electronic prosthesis. Prog Brain Res. 2009;175:317-32.
3. Mokwa W, Goertz M, Koch C, et al. Intraocular epiretinal prosthesis to restore vision in blind humans. Conf Proc IEEE Eng Med Biol Soc. 2008;2008:5790-3.

References – Update June 2009

1. Artificial Retina Project. Last updated March 2009.

References – Update June 2008

1. Artificial Retina Project. Last updated 2008 Feb.

References

1. Chow AY, Chow VY, Packo KH, et al. The artificial silicon retina microchip for the treatment of vision loss from retinitis pigmentosa. Arch Ophthalmol. 2004 Apr;122(4):460-9.
2. Yanai D, Weiland JD, Mahadevappa M et al. Visual performance using a retinal prosthesis in three subjects with retinitis pigmentosa. Am J Ophthalmol. 2007 May;143(5):820-827
3. U.S.National Institutes of Health Clinical Trials. Argus II Retinal Stimulation System Feasibility Protocol. Second Sight.
4. Alteheld N, Roessler G, Vobig M, Walter P. The retina implant--new approach to a visual prosthesis. Biomed Tech (Berl). 2004 Apr;49(4):99-103.
5. Dowling J. Artificial human vision. Expert Rev Med Devices. 2005 Jan;2(1):73-85.
6. Hughes B, Ratnakaram R. ARMD, Retinal Electronic Prosthesis and RPE Transplantation. EMedicine. Last Updated. Jan. 2007.
7. Breault Research Organization. Optoelectronic implants to treat visual diseases. Optics Report: Healthcare. Updated June 14, 2003.
8. Gekeler F, Zrenner E. Status of the subretinal implant project. An overview. Ophthalmologe. 2005 Oct;102(10):941-9.

9. Gerding H. A new approach towards a minimal invasive retina implant. J Neural Eng. 2007 Mar;4(1):S30-7.
10. Hamel C. Retinitis pigmentosa. Orphanet J Rare Dis. 2006 Oct 11;1:40.
11. Javaheri M, Hahn DS, Lakhanpal RR, et al. Retinal prostheses for the blind. Ann Acad Med Singapore. 2006 Mar; 35(3):137-44.

Important Notice

General Purpose.

Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net's National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member's benefits contract as described in this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to practice medicine.

Policy Effective Date and Defined Terms.

The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, prior notice or posting on the website is required before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

Policy Amendment without Notice.

Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, prior notice or website posting is required before an amendment is deemed effective.

No Medical Advice.

The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

No Authorization or Guarantee of Coverage.

The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

Policy Limitation: Member's Contract Controls Coverage Determinations.

Statutory Notice to Members: The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member's contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member's contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member's contract shall govern. The Policies do not replace or amend the Member's contract.

Policy Limitation: Legal and Regulatory Mandates and Requirements

The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

Reconstructive Surgery

CA Health and Safety Code 1367.63 requires health care service plans to cover reconstructive surgery. "Reconstructive surgery" means surgery performed to correct or repair abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease to do either of the following:

- (1) To improve function or
- (2) To create a normal appearance, to the extent possible.

Reconstructive surgery does not mean "cosmetic surgery," which is surgery performed to alter or reshape normal structures of the body in order to improve appearance.

Requests for reconstructive surgery may be denied, if the proposed procedure offers only a minimal improvement in the appearance of the enrollee, in accordance with the standard of care as practiced by physicians specializing in reconstructive surgery.

Reconstructive Surgery after Mastectomy

California Health and Safety Code 1367.6 requires treatment for breast cancer to cover prosthetic devices or reconstructive surgery to restore and achieve symmetry for the patient incident to a mastectomy.

Coverage for prosthetic devices and reconstructive surgery shall be subject to the co-payment, or deductible and coinsurance conditions, that are applicable to the mastectomy and all other terms and conditions applicable to other benefits. "Mastectomy" means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

Policy Limitations: Medicare and Medicaid

Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.